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To Examiner: Mina Haghighatian
Group 1616

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Docket No.: 2685.1003-008 (US3)
Appellants: David A. Edwards, et al.
Serial No.: 09/822,716
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/822,716 Confirmation No.: 7248
Appellants : David A. Edwards and Jeffrey S. Hrkach
Filed : March 30, 2001
TC/A.U. : 1616
Examiner : Mina Haghighatian

Docket No. : 2685.1003-008 (US3)
Customer No. : 000038421
Title : PARTICLES FOR INHALATION HAVING SUSTAINED
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REPLY BRIEF

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Sir:

This Reply Brief is being filed pursuant to Rule 41.41 in response to the Examiner's Answer mailed May 13, 2005. The Brief filed on December 22, 2004 is incorporated herein by reference.

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The Examiner's Answer, for the first time, argues that "Jensen teaches that precipitation results in a 'better' stability profile than powders of essentially the same composition prepared by spray drying. A preferred embodiment is not teaching away from the broadest disclosure." Appellants disagree.

Jensen is not directed to spray drying formulations, either as a preferred embodiment or non-preferred embodiment. Jensen is directed to a "process for the preparation of a therapeutic powder formulation..." See the Field of the Invention. That process is described, for example, in the Summary at Column 2, lines 41-54. This is not just a preferred embodiment. It is the invention of Jensen. This invention is taught to have advantages over prior art processes of spray drying and freeze spray drying. Spray drying and freeze spray drying are not non-preferred embodiments of Jensen. Jensen teaches away from spray drying and freeze spray drying. One of ordinary skill in the art would simply not look to a spray drying reference (e.g., Weers) or freeze spray drying reference (e.g., Maa) to identify physical characteristics to modify the products of Jensen nor would such a combination teach one how to modify Jensen's process to produce such products. Further, it simply isn't understood how the Examiner concludes that one of ordinary skill in the art would be motivated, given the teachings of Jensen, to spray dry or spray freeze dry the "Jensen formulation."

Perhaps the failings of the rejection can be illustrated in a different way. The rejection does not state how one is to combine the teachings of Jensen with Maa and Weers. That is, even if one were motivated to combine the references, *how* does the Examiner believe one is to accomplish the combination? Is one to spray dry or spray freeze dry the "Jensen formulation" to achieve the products having the physical characteristics of Maa and Weers while preserving the fundamental objectives taught by Jensen? If so, where in Jensen does it teach that his *process* is not an essential limitation of his invention but merely a preferred embodiment to be employed at the artisan's discretion? Where in Jensen is it taught how to achieve the properties of his products by another materially different process? Or, is one to precipitate the "Jensen formulation" in accordance with the "Jensen process" in a manner which accomplishes the physical parameters of Maa and Weers? If so, where in Jensen, Maa and Weers is it taught those

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process conditions of Jensen that are to be modified to achieve this result? The person of ordinary skill in the art would not combine these references as proposed by the Examiner.

For the first time in the Answer, the Examiner states that the particle size can be achieved by milling and that the specification does not teach that spray drying provides control over size and density. While milling can reduce the geometric diameter or particle size of a particle population, it does not ensure that the particle population possesses a low density. Further, it does not ensure that all three physical characteristics are satisfied (i.e., a geometric diameter of between 5 and 30 microns, an aerodynamic diameter between 1 and 5 microns and a tap density of less than 0.4 g/cm³). All of the prior art references agree that the process has a substantial impact upon the physical properties and characteristics of the product. For example, one would not expect a precipitation process, such as Jensen's, to achieve hollow spheres made by Weers.

The Examiner is unconvinced by the above observation, stating that the claims do not recite the morphology. While it is true that the claims do not recite the particle morphology (spheres or not), it is clear that, when considering the motivation to combine the references, the observation is relevant. Since Weers is directed to making spheres, which cannot be made by Jensen's precipitation process, one wouldn't turn to Jensen to make the products of Weers.

The Examiner's rebuttal evidences the impermissible hindsight reconstruction of the rejection. The Examiner picks and chooses sentences from the references to show that the elements of the claims are found in the prior art. The Examiner ignores the teachings of the references that suggest that the references cannot be combined by comparing the teachings with the claims. Thus, the Examiner is not considering the teachings of the references as a whole to determine whether or not one would be motivated to *combine* the references to arrive at an embodiment that will satisfy the claim elements. She only considers those teachings that show that the various elements of the claims are known and then concludes that, somehow, one would combine the teachings to arrive at the claims.

It is noted that the Examiner states throughout the Answer that the particles of the claims have a diameter between 1 and 5 microns. This may be confusing. The median

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geometric diameter of the claimed particles is between 5 and 30 microns (MMGD). The median aerodynamic diameter is between 1 and 5 microns (MMAD). Of course, the aerodynamic diameter is not the actual physical size of a particle but describes the way the particle behaves. The geometric diameter, aerodynamic diameter and density are mathematically related. See page 21 of the specification. Thus, the claims are directed to large porous particles with a low aerodynamic diameter. Jensen is directed to small particles.

Reversal of the rejections is requested.

Respectfully submitted,



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